Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing remarks, claims 1-2 and 4-17 are pending in the application, of which claims 1, 4, 10 and 12 are independent

Based on the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 101

In paragraph 3 of the Office Action, the Examiner states that claims 1-2 and 4-17 are directed to abstract ideas. Further, the Examiner states that there is no pre-processing or post-processing of real world data. 35 U.S.C. § 101, the MPEP and the Federal Circuit cases that focus on this statute, do not require pre-processing or post processing of real world data. Rather, § 101 merely requires that the invention be a new and useful process, machine, manufacture or composition of matter. The Examiner appears to be presenting an old, outdated argument regarding software and business methods. However, the Federal Circuit made clear in *State Street Bank* that software and methods of doing business are statutory under § 101. *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998). The claimed invention is a process for simulating solution preparation in a biopharmaceutical production process, which generates a solution preparation schedule wherein each task associated with the preparation of a solution in the biopharmacedutical production process is scheduled. The schedule is generated after considering a number of factors. The schedule is used to determine an optimal design for

a biopharmaceutical batch process manufacturing facility. Such a process is clearly not abstract and therefore is statutory under § 101.

The Examiner has also asserted the claimed invention lacks utility under 35 U.S.C. §§ 101 and 112, first paragraph. Applicants respectfully traverse this rejection as well. Applicants do not understand the Examiner's rejection since the utility is specifically recited in the claim - optimizing the design for a biopharmaceutical batch process manufacturing facility. Accordingly, Applicant respectfully requests that claims 1-2 and 4-17 be reconsidered, and that these rejections be withdrawn.

Rejections under 35 U.S.C. § 112 (2)

In paragraph 7 of the Office Action, the Examiner has rejected claims 1-2 and 4-17 under 35 U.S.C. § 112, second paragraph, as being indefinite because of the term "optimal" and as being incomplete for omitting essential steps under MPEP 2172.01. Applicants respectfully traverse this rejection.

First, the term optimal is used in a whereby clause. This clause merely provides a use of the recited solution preparation schedule. Optimal is defined as most favorable or desirable, which changes depending on the circumstances (e.g., the type of manufacturing facility). The term as used in the claim, however, is not vague or indefinite.

Second, the claim does not omit essential steps. The claim recites a series of steps that culminate in a solution preparation schedule being generated. The whereby clause merely provides a use for this schedule, as would be apparent to one skilled in the art after readings the claims and the corresponding text from Applicant's application. Accordingly,

Applicant respectfully requests that claims 1-2 and 4-17 be reconsidered, and that this rejection be withdrawn.

Rejections under 35 U.S.C. § 103

In paragraph 11 of the Office Action, the Examiner has rejected claims 1-2 and 4-17 under 35 U.S.C. § 103 as being unpatentable over:

a) Skeirik, **or** Atherton, **or** Iwasaki *et al.*, **or** Litt *et al.*, **or** Furukawa *et al.*, **or** Carrette *et al.*, **or** Leitch *et al.*, **or** Ketcham *et al.*, **or** Bernstein *et al.*, **or** Ehrlich *et al.*, **or** Arai *et al.*, **or** Britt *et al.*, in view of:

b) Examiner's Official Notice; and

c) Examiner's assertion of an admission on the part of the Applicant.

This rejection is traversed below.

The references of part a) (above) cited in the rejection all deal with various process systems for manufacturing facilities. In contrast, the present invention is directed to simulating the scheduling of solution preparation in a biopharmaceutical production process in order to arrive at an optimal facility design. Each of the references of above-labeled section a) are herein discussed:

Skeirik appears to teach an integrated process control system (IPS) developed for a substantially continuous process. Skeirik appears to focus on maintaining product quality by 1) allowing storage of data histories collected from in process sensors and off-line analytical tests from previous shifts and 2) the development of what Skeirik calls expert system routines that adjust on-line process parameters in real-time based on this historical

and real-time process measurement. This appears to be done to maintain product quality goals.

Considering claim 1, for example, Skeirik does not teach or suggest at least the fifth step of generating a solution preparation schedule wherein each tasks associated with the preparation of said at least one solution in the biopharmaceutical production process is scheduled; whereby the simulation can be used to determine an optimal design for a biopharmaceutical batch process manufacturing facility.

Atherton appears to teach a manufacturing scheduling system for distributed manufacturing industries. Atherton appears to concern itself with the queuing and routing of materials to numerous workstations (e.g., lathes, metal presses, etc.) at any given time. Because orders for products fluctuate in both quantity and type, Atherton appears to consider product delivery times and prioritization parameters.

Considering claim 1, for example, Atherton does not teach or suggest at least the fifth step of generating a solution preparation schedule wherein each tasks associated with the preparation of said at least one solution in the biopharmaceutical production process is scheduled; whereby the simulation can be used to determine an optimal design for a biopharmaceutical batch process manufacturing facility.

Iwaski appears to teach a production system for semiconductor wafer manufacturing in a distributed manufacturing format that attempts to improve material handling systems for wafer transportation between workstations (i.e., in light of new wafer product characteristics). Iwaski appears to establish an order of processing priority for different products in a buffering system between workstations. As with Atherton above, Iwasaki

appears to concern itself with managing queuing and routing operations of products through various workstations.

Considering claim 1, for example, Iwaski does not teach or suggest at least the fifth step of generating a solution preparation schedule wherein each tasks associated with the preparation of said at least one solution in the biopharmaceutical production process is scheduled; whereby the simulation can be used to determine an optimal design for a biopharmaceutical batch process manufacturing facility.

Litt appears to teach the planning of a firing furnace processing different batches of parts in different combinations based on irregular part orders. Litt appears to be concerned with the delivery dates and product configurations of a single workstation, that is, the firing furnace.

Considering claim 1, for example, Litt does not teach or suggest at least the fifth step of generating a solution preparation schedule wherein each tasks associated with the preparation of said at least one solution in the biopharmaceutical production process is scheduled; whereby the simulation can be used to determine an optimal design for a biopharmaceutical batch process manufacturing facility.

Furukawa appears to teach a production control system for an automated assembly line process that fabricates many kinds of products such as electronic devices in small quantities within short delivery times. Furukawa appears to teach a system that relies on corrective measures to adjust schedules when an event disrupts the production line.

Considering claim 1, for example, Furukawa does not teach or suggest at least the fifth step of generating a solution preparation schedule wherein each tasks associated with the preparation of said at least one solution in the biopharmaceutical production process is

scheduled; whereby the simulation can be used to determine an optimal design for a biopharmaceutical batch process manufacturing facility.

Carrette appears to teach a digital processing method and apparatus that allows supervisory control of manufacturing processes in real time. The method and apparatus of Carrette appears to function by gathering data from in-process sensors, tags that data with a time stamp, allows a user to assign an expiration time value to the data, and the ability to store the data for process and response calculations to modify the process.

Considering claim 1, for example, Carrette does not teach or suggest at least the fifth step of generating a solution preparation schedule wherein each tasks associated with the preparation of said at least one solution in the biopharmaceutical production process is scheduled; whereby the simulation can be used to determine an optimal design for a biopharmaceutical batch process manufacturing facility.

Leitch appears to teach a real-time process control system that allows a user to establish rules for eliciting a response to various inputs from the process as it runs. Leitch appears to teach a system that allows the development of response rules based on operator experience that can be used by the system to respond to measure process variables in real-time.

Considering claim 1, for example, Leitch does not teach or suggest at least the fifth step of generating a solution preparation schedule wherein each tasks associated with the preparation of said at least one solution in the biopharmaceutical production process is scheduled; whereby the simulation can be used to determine an optimal design for a biopharmaceutical batch process manufacturing facility.

Ketcham appears to teach a system for simulating continuous flow processes in manufacturing. Ketcham does not appear to teach rules for optimizing the utilization of process equipment.

Considering claim 1, for example, Ketcham does not teach or suggest at least the fifth step of generating a solution preparation schedule wherein each tasks associated with the preparation of said at least one solution in the biopharmaceutical production process is scheduled; whereby the simulation can be used to determine an optimal design for a biopharmaceutical batch process manufacturing facility.

Bernstein appears to teach the development of a process simulation tool applied to a human plasma fractionation process. Bernstein appears to disclose in bare terms a simulation and database. Bernstein does not appear to teach or suggest the scheduling processes of the present invention, nor the factors, such as equipment utilization factors, upon which such scheduling processes can depend.

Considering claim 1, for example, Bernstein does not teach or suggest at least the fifth step of generating a solution preparation schedule wherein each tasks associated with the preparation of said at least one solution in the biopharmaceutical production process is scheduled; whereby the simulation can be used to determine an optimal design for a biopharmaceutical batch process manufacturing facility.

Ehrlich appears to disclose a general description of the FACTOR/AIM simulator marketed by the Pritsker Corporation as applied in distributed manufacturing.

Considering claim 1, for example, Ehrlich does not teach or suggest at least the fifth step of generating a solution preparation schedule wherein each tasks associated with the preparation of said at least one solution in the biopharmaceutical production process is

scheduled; whereby the simulation can be used to determine an optimal design for a biopharmaceutical batch process manufacturing facility.

Arai appears to teach an automatic analysis system that focuses on ascribing a unique identification number to each piece of analytical information required, as well as a method to group information in multiple levels with additional identification numbers being assigned to respective groups in a manner that facilitates automated processing of analytical samples.

Considering claim 1, for example, Arai does not teach or suggest at least the fifth step of generating a solution preparation schedule wherein each tasks associated with the preparation of said at least one solution in the biopharmaceutical production process is scheduled; whereby the simulation can be used to determine an optimal design for a biopharmaceutical batch process manufacturing facility.

Britt appears to teach a system for process simulation that checks for the type of equipment needed and use generated data to refine the simulation.

Considering claim 1, for example, Britt does not teach or suggest at least the fifth step of generating a solution preparation schedule wherein each tasks associated with the preparation of said at least one solution in the biopharmaceutical production process is scheduled; whereby the simulation can be used to determine an optimal design for a biopharmaceutical batch process manufacturing facility.

Applicant respectfully disagrees with the Examiner's Official Notice that one of ordinary skill in the art at the time of the invention would recognize and choose the appropriate process and quality control variables as necessary for the particular application.

Applicant feels that these asserts are both broad and vague. For similar reasons, Applicant respectfully disagrees with the Examiner's prior Official Notice.

The Examiner will now find that the present invention, as clarified above with regard to claims 1-2 and 4-17, is not obvious in light of these references either taken alone or in combination. Accordingly, Applicant respectfully requests that claims 1-2 and 4-17 be reconsidered, and that this rejection be withdrawn.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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